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Original Article

Organ Preservation Using Contact Radiotherapy for Early Rectal Cancer: Outcomes of Patients Treated at a Single Centre in the UK

A.S. Dhadda, A. Martin, S. Killeen, I.A. Hunter

Queen's Centre for Oncology & Haematology, Castle Hill Hospital, Hull, UK

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Abstract

Aims: Contact radiotherapy for early rectal cancer uses 50 kV X-rays to treat rectal cancers under direct vision. We present data of a series of patients treated at a single centre with prospective follow-up and functional assessment.

Materials and methods: All patients were treated at the Queen's Centre for Oncology, Hull, UK between September 2011 and October 2015. Patients received a biopsy, magnetic resonance imaging (MRI) of the liver/pelvis, computed tomography of the chest and endorectal ultrasound. Patients were deemed to be either unfit for radical surgery or refused it due to the need for a permanent stoma. Follow-up consisted of 3 monthly flexible sigmoidoscopy and MRI of the liver/pelvis and 12 monthly computed tomography of the chest.

Results: In total, 42 patients were treated with contact radiotherapy \pm external beam chemo/radiotherapy without any primary surgical excision. The median age was 78 years (range 50–94 years). Local recurrence-free survival was 88%, disease-free survival was 86% and overall survival was 88% with a median follow-up of 24 months (range 5–54 months). The median time to recurrence was 12 months (range 4–14 months). The estimated 30 day surgical mortality for this cohort with radical surgery was 12%. Mortality from the contact radiotherapy procedure was 0%. Functional outcomes as investigated by the Low Anterior Resection Syndrome (LARS) score were good, with 65% having no LARS.

Conclusions: Contact radiotherapy for early rectal cancer is a safe, well-tolerated outpatient procedure, allowing organ preservation, with excellent oncological and functional outcomes. For elderly co-morbid patients with suitable rectal cancers this should be considered as a standard of care.

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Key words: Organ preservation; radiotherapy; rectal cancer

Introduction

Rectal cancer is common, with 12 000 registered cases in the UK per annum [1]. Over the last two decades, improvements in radiology, surgery and neoadjuvant radiotherapy have resulted in marked reductions in local recurrence in rectal cancer without necessarily any improvements in overall survival [2–4]. Radical surgery in the form of a total mesorectal excision is considered the gold standard treatment in operable rectal cancer notwithstanding a growing awareness of putative negative long-term quality of life implications [5]. However, an older co-morbid population represent a higher operative risk group, while the advent of bowel cancer screening

programmes should increase the number of early rectal cancers diagnosed. These two distinct rectal cancer cohorts embody patients potentially amenable to an organ preservation approach.

Since the landmark paper of Habr-Gama *et al.* [6], detailing a wait and see policy in complete responders to chemoradiotherapy for rectal neoplasms, there is a mounting vogue for organ preservation in selected patients. This strategy has now expanded to include local excision (transanal excision, endoscopic submucosal resection, transanal endoscopic excision or transanal minimally invasive surgery TAMIS), contact radiotherapy, external beam chemo/radiotherapy as standalone monomodal therapies or various collective stratagems.

Local excision of small early rectal cancers is now increasing, although as a single modality for patients with T2 rectal cancer this would amount to an oncological compromise [7,8]. Contact radiotherapy, as described by

Author for correspondence: A.S. Dhadda, Queen's Centre for Oncology & Haematology, Castle Hill Hospital, Castle Road, Cottingham, Hull, UK.

E-mail address: Amandeep.Dhadda@hey.nhs.uk (A.S. Dhadda).

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Papillon [9], using 50 kV X-rays has been shown in several case series to provide reasonable local recurrence and disease-free survival rates for selected patients without surgery [9–11]. Nevertheless these reports have suffered to some degree from uncertain selection criteria, lack of modern day radiological staging, retrospective data, varying schedules of radiotherapy dose/fractionation, lack of standardised surveillance protocols or robust functional data.

Here we present our unique series of patients treated using contact radiotherapy at a single centre in a modern era with prospective follow-up and functional assessment data.

Materials and Methods

The contact radiotherapy service at the Queens Centre of Oncology and Haematology, Hull, UK started on 11 September 2011, providing tertiary referral services for contact radiotherapy for rectal cancer. We present data for patients treated up to 1 October 2015, with data analysed at 4 January 2016. All patients were discussed at a multidisciplinary team meeting with pretreatment work-up generally consisting of flexible sigmoidoscopy/colonoscopy with biopsy, computed tomography of the chest, magnetic resonance imaging (MRI) of the liver, diffusion-weighted MRI of the pelvis and endorectal ultrasound.

The *a priori* selection criteria for local treatment are detailed in Table 1. All patients included were counselled that total mesorectal excision constituted gold standard therapy. Local treatment was reserved for patients refusing radical surgery due to the need for a permanent stoma or for those with prohibitive operative risks from radical surgery related to pre-existing medical co-morbidities.

Early biopsy proven invasive adenocarcinomas less than 3 cm in diameter were treated with contact radiotherapy followed in most cases by external beam (chemo)/radiotherapy to the pelvis to treat potential involved occult mesorectal nodes. In patients with larger tumours, initial external beam chemo/radiotherapy was given to allow regression before contact radiotherapy. External beam radiotherapy volumes were confined to treat the mesorectum and generally did not go above S2/3. No patients had

local surgical excision either before or after radiotherapy treatment. Furthermore, no adjuvant chemotherapy was routinely given after radiotherapy treatment.

The schedule of dose/fractionation is shown in an algorithm in Figure 1.

Contact radiotherapy was carried out in an outpatient setting. Enemas were given before the procedure to clear the low rectum, with topical local anaesthetic (lidocaine 2%) gel and glycerol trinitrate cream applied around the anal canal for patient comfort. Patients were commonly treated in lithotomy position with the knee/chest position deployed for anteriorly placed tumours. Shrinking fields were not used. All patients were treated using the Arianne Papillon 50 machine using 50 kV X-rays. Fractions were separated using 2 week intervals.

Following the completion of treatment, patients were assessed at 6 weeks with diffusion-weighted MRI of the liver/pelvis and flexible sigmoidoscopy. These were repeated at 3 monthly intervals with 12 monthly computed tomography of the chest carried out to screen for distant disease for the first 24 months. Thereafter the frequency of investigations reduced, with patients having 6 monthly flexible sigmoidoscopies and MRI scans of the liver/pelvis.

Treatment-related toxicity was graded using Common Toxicity Criteria, whereas functional outcomes were assessed after treatment using the previously validated patient administered Low Anterior Resection Syndrome (LARS) score [12,13].

The American Society of Anaesthesiologists score was used to categorise the patient's prospective operative risk [14]. The risk prediction model for oncological colorectal resections produced by Tekkis *et al.* [15] was then used to estimate 30 day mortality in these patients had they proceeded to radical surgery.

Results

Between 11 September 2011 and 1 October 2015, 42 patients were treated using the schedule and technique described above. The median age of patients was 78 years (range 50–94 years), with other demographics shown in Table 2. The median follow-up was 24 months (range 5–53 months). Of these patients, 24 (57%) were considered high

Table 1
Indications for contact radiotherapy

Indications for local treatment	Indications for Contact Radiotherapy
Mobile non-ulcerative exophytic tumour Tumour < 3cm and occupying less than one third of circumference cT1N0M0 Well/mod differentiated	Patients who refuse surgery and fulfil local treatment criteria Medically inoperable patients who fulfil local treatment criteria
No lymphovascular or venous invasion	Patients with low risk pT1 SM2 tumours post local resection Patients with pT1 SM3 or pT2 tumours post local resection who are unfit for radical resection Medically unfit patients with tumours >3cm or more advanced tumours (cT3) who show a good response to initial external beam radiotherapy

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